JUDGE KARAS

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

08 CV 3130

BRENDA DANNS,

Plaintiff,

-against-

DAVOL INC. and C.R. BARD, INC.,

Defendants.

DOCKET NO.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff BRENDA DANNS (alternatively referred to as "Plaintiff"), by and through her attorneys PARKER WAICHMAN ALONSO, LLP, hereby sues the defendants, DAVOL INC. and C.R. BARD, INC., (hereinafter collectively referred to as "Defendants"), and alleges as follows:

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U.S. DISTRICT COURT
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BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Bard® Composix® Kugel® Mesh Hernia Repair Patch (hereinafter referred to as the "Kugel Hernia Patch").

2. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Kugel Hernia Patch for use in repairing ventral and incisional hernias.

3. Due to the defective nature of the Kugel Hernia Patch, the Food and Drug Administration (hereinafter referred to as "FDA") was forced to issue a Class I recall of the product on three separate occasions since December 22, 2005.

4. As a result of the defective nature of the Kugel Hernia Patch, those persons who received and/or rely on the Kugel Hernia Patch have suffered and/or are at an increased risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and/or such other side effects as serious infection, the need for additional surgery to remove and/or replace the defective product, and/or the need for subsequent surgery to repair perforations caused by the defective product, as well as other severe and permanent health consequences as a result of their defective product.

5. Defendants concealed their knowledge of the defects in their products from the Plaintiff and Plaintiff's physicians and hospital and the FDA.

6. Consequently, Plaintiff seeks compensatory and punitive damages as a result of her use of the Kugel Hernia Patch, which has caused, may cause, and/or will continue to cause Plaintiff to suffer physical pain, mental anguish, medical, and other expenses.

JURISDICTION & VENUE

7. This Court has jurisdiction pursuant to 28 United States Code Section 1332, in that Plaintiff is a citizen of a State which is different from the States where Defendants are incorporated and have their principal places of business.

8. The amount in controversy exceeds SEVENTY-FIVE THOUSAND DOLLARS ($75,000.00), exclusive of interest and costs.

9. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in the district as Plaintiff underwent surgery to repair a large incisional hernia in this district in which the Kugel Hernia Patch was used to repair the defect. Further, venue is proper in this judicial district because the Defendants are doing business in this judicial district.

10. Plaintiff is a natural person and a resident of the State of New York.

11. This diversity action is brought pursuant to violations of the General Business Law §§ 349 and 350 and the common law of the State of New York and all other applicable laws to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, for the injuries the Plaintiff has sustained as a result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling, and/or sale of the Kugel Hernia Patch.

PARTY PLAINTIFF

12. Plaintiff is a citizen of the United States of America, and is a citizen and resident of the State of New York.

PARTY DEFENDANTS

13. Upon information and belief, Defendant DAVOL INC. ("DAVOL") is incorporated in the state of Rhode Island, with its principal place of business located at 100 Sockanosset Crossroad, Cranston, Rhode Island.

14. Upon information and belief, Defendant DAVOL, has transacted and conducted business in the State of New York and throughout the United States.

15. Upon information and belief, Defendant DAVOL, has derived substantial revenue from goods and products used in the State of New York and throughout the United States.

16. Upon information and belief, Defendant DAVOL, expected or should have expected its acts to have consequence within New York and throughout the United States, and derived substantial revenue from interstate commerce within the United States, and New York, more particularly.

17. Defendant DAVOL focuses its business on products in key surgical specialties,

including hernia repair, hemostasis, orthopedics, and laparoscopy.

18. Upon information and belief, and at all relevant times, Defendant DAVOL, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Kugel Hernia Patch for use in repairing ventral and incisional hernias.

19. Upon information and belief, Defendant C.R. BARD, INC. ("BARD"), is incorporated in the State of New Jersey, with its principal place of business located at 730 Central Avenue, Murray Hill, New Jersey 07974.

20. Upon information and belief, Defendant, BARD, has transacted and conducted business in the State of York and throughout the United States.

21. Upon information and belief, Defendant, BARD, has derived substantial revenue from goods and products used in the State of New York and throughout the United States.

22. Upon information and belief, Defendant, BARD, expected or should have expected their acts to have consequence within the State of New York and throughout the United States, and derived substantial revenue from interstate commerce within the United States, and New York, more particularly.

23. BARD is the corporate parent/stockholder of DAVOL.

24. Upon information and belief, Defendant, DAVOL was acquired by Defendant, BARD, in 1980, at which point DAVOL became a wholly-owned subsidiary of Defendant, BARD.

25. Upon information and belief, and at all relevant times, Defendant, BARD, manufactures, sells and distributes the Kugel Hernia Patch through its wholly-owned subsidiary, Defendant, DAVOL.

26. BARD also manufactures and supplies DAVOL with material that forms part of

the Kugel Hernia Patch.

FACTUAL ALLEGATIONS

27. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Kugel Hernia Patch for use in repairing ventral and incisional hernias.

28. Upon information and belief, Defendants had sales in 2004 from their Surgical Specialties segment of business, which includes the Kugel Hernia Patch, in excess of three hundred and thirteen million dollars ($313,000,000).

29. Upon information and belief, Defendants had sales in 2005 from their Surgical Specialties segment of business, which includes the Kugel Hernia Patch, in excess of three hundred and thirty million dollars ($330,000,000).

30. Upon information and belief, Defendants had sales in 2006 from their Surgical Specialties segment of business, which includes the Kugel Hernia Patch, in excess of three hundred and fifty-seven million dollars ($357,000,000).

31. Upon information and belief, Defendants are in the market for ventral and incisional hernia repair products.

32. The Defendants submitted their 510k Application for the Kugel Hernia Patch to the Federal Drug Administration (hereinafter referred to as the "FDA") on January 22, 2001. Following this 510k Application, the Kugel Hernia Patch was authorized by the FDA as a Class II medical device.

33. Upon information and belief, Defendants' Kugel Hernia Patch is a self-expanding patch used to repair ventral and incisional hernias.

34. The Kugel Hernia Patch is placed behind the hernia through an incision.

35. The Kugel Hernia Patch contains a "memory recoil ring" that allows the patch to be folded for insertion and later spring open and lay flat once it is in place.

36. The alleged purpose of the Kugel Hernia Patch, once it is inside, is to allegedly stimulate tissue growth and allegedly reduce the risk of recurrent hernias.

37. Upon information and belief, the Kugel Hernia Patch was originally approved for sale and use by the FDA on or about January 22, 2001. The FDA's decision for approval was based upon information provided to them by Defendants.

38. Upon information and belief, Defendants introduced the Kugel Hernia Patch to the market on or about February 9, 2001.

39. Soon after the Kugel Hernia Patch was placed on the market, the Defendants began receiving actual notices of Kugel Hernia Patch defects and failures.

40. The Defendants actively and intentionally disregarded these complaints and concerns of the physician surveyors from Plaintiff, Plaintiff's physicians and the public at large.

41. Not only was there no device history record (DHR) review performed – as called for by protocol – but the Defendants also actively and intentionally concealed these notices concerning defective and dangerous conditions(s) associated with the Kugel Hernia Patch from Plaintiff, Plaintiff's physicians and the general public.

42. After the defective and dangerous Kugel Hernia Patch was already placed on the market, Defendants conducted physician screenings and reviews beginning in 2002.

43. Furthermore, an Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this time.

44. Whether intentionally or negligently, the Defendants failed to properly conduct

and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results.

45. According to protocol, these surveys and reviews were needed before placing the devices on the open market.

46. On December 22, 2005 the FDA issued an immediate Class I recall of the "Extra Large Oval" sizes of the Kugel Hernia Patch.

47. A Class I recall is the most serious recall that the FDA can issue and is issued when there is a reasonable chance that the medical device could cause serious health problems or death.

48. The December 22, 2005 recall was based on defective "memory recoil rings."

49. These "memory recoil rings" can "break under the stress placed on these products during placement of the large sized products in the intra-abdominal (inside the belly area) space. This can lead to bowel perforations and/or chronic intestinal fistulae." *See* U.S. Food and Drug Administration, *Class I Recall: Bard® Composix® Kugel® Mesh Patch—Expansion* (2007), http://www.fda.gov/ cdrh/recalls/recall-122205.html.

50. On March 31, 2006 the FDA expanded the list of recalled Kugel Hernia Patches to include all lots of Oval Patches (6.3" * 12.3") and specific lots of Large Oval and Large Circle Patches.

51. On January 24, 2007 the FDA further expanded the list of recalled Kugel Hernia Patches to include additional lots of Large Oval and Large Circle Patches.

52. Upon information and belief, further and additional Kugel Hernia Patches will likely be recalled.

53. Upon information and belief, Defendants did not have adequate and appropriate systems in place to collect and analyze any of the complaints they received from doctors, hospitals, and/or patients concerning the Kugel Hernia Patch, as required by the FDA, thus leading to inconsistencies and irregularities in the way Defendants kept track of complaints they received regarding the failure of the Kugel Hernia Patch.

54. Upon information and belief, Defendants knew, or should have known, of the seriousness of the risks of using the Kugel Hernia Patch based upon the state of knowledge of the Kugel Hernia Patch as it existed at that time, and upon generally accepted medical and research standards and principles.

55. Upon information and belief, Defendants knew, or should have known, of the seriousness of the risks of using the Kugel Hernia Patch based upon the complaints they received from doctors, hospitals, and/or patients who used the Kugel Hernia Patch demonstrating that the product was defective.

56. Upon information and belief, Defendants failed to send the necessary product failure reports to the FDA, as required by the FDA, indicating that the Kugel Hernia Patch was causing serious and fatal injuries in persons who used the Kugel Hernia Patch.

57. Defendants failed to appropriately and adequately warn Plaintiff and Plaintiff's physicians, hospitals, and the FDA, of the serious and dangerous risks involved in using Defendants' Kugel Hernia Patch, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences.

58. Upon information and belief, Defendants misrepresented the known risks inherent in the use of the Kugel Hernia Patch.

59. Defendants made certain claims which were distributed and circulated to the medical and healthcare professions that the Kugel Hernia Patch was safe.

60. Defendants were careless and negligent in the manufacturing, testing, selling, distribution, merchandising, advertising, marketing, promotion, compounding, packaging, fabrication, warning, analyzing, marketing, and recommendation of the Kugel Hernia Patch.

61. By reason of the foregoing, Plaintiff has suffered and/or is at extremely high risk of suffering serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences.

62. On or about April 1, 2005, Plaintiff underwent surgery to repair a large incisional hernia. The Kugel Hernia Patch was used to repair the defect.

63. The Kugel Hernia Patch used in Plaintiff was subject to and part of the FDA recall.

64. As result of using Defendants' Kugel Hernia Patch, Plaintiff was caused to suffer, among other injuries, abdominal infection, and was hospitalized and caused to undergo additional surgeries and caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

65. The injuries sustained by Plaintiff were due to the Defendants' Kugel Hernia Patch.

66. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious dangerous side effects.

67. As alleged herein, as a direct and proximate result of the Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the Kugel Hernia Patch, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

COUNT I
PRODUCT LIABILITY – NEGLIGENCE

68. Plaintiff incorporates by reference paragraphs 1 through 67 above, as though fully set forth herein.

69. Defendants were negligent to Plaintiff in the following respects:

70. The Defendants at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Kugel Hernia Patch.

71. The Defendants at all times mentioned knew or in the exercise of reasonable care should have known, that the Kugel Hernia Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold supplied, prepared and/or provided with the proper warnings, and were unreasonably likely

to injure the Kugel Hernia Patch's users.

72. The Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Kugel Hernia Patch, that they were dangerous and unsafe for the use and purpose for which it was intended.

73. The Defendants were aware of the probable consequences of the Kugel Hernia Patch.

74. The Defendants knew or should have known the Kugel Hernia Patch would cause serious injury, however, they failed to disclose the known or knowable risks associated with the Kugel Hernia Patch.

75. The Defendants willfully and deliberately failed to avoid those consequences, and in doing so, they acted in conscious disregard of the safety of the Plaintiff.

76. The Defendants owed a duty to the Plaintiff to adequately warn her and her treating physicians, of the risks of breakage, separation, tearing and splitting associated with the Kugel Hernia Patch and the resulting harm and risk it would cause patients.

77. The Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Kugel Hernia Patch.

78. As a direct and proximate result of the duties breached, the Kugel Hernia Patch used in the Plaintiff's hernia repair surgery failed, resulting in the Plaintiff suffering serious injury, pain and harm.

79. As a direct and proximate result of the Defendants' negligence, the Plaintiff has

suffered injuries and damages.

80. The Defendants' conduct in continuing to market, sell and distribute the Kugel Hernia Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter the Defendants and others from similar conduct in the future.

81. As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN

82. Plaintiff incorporates by reference paragraphs 1 through 81 above, as though fully set forth herein.

83. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Kugel Hernia Patch.

84. The Kugel Hernia Patch is defective and unreasonably dangerous to consumers.

85. The Kugel Hernia Patch is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

86. At all times material to this action, the Kugel Hernia Patch was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including Plaintiff herein, without substantial change in the condition in which it was sold.

87. At all times material to this action, the Kugel Hernia Patch was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Kugel Hernia Patch contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the Kugel Hernia Patch, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences;

b. When placed in the stream of commerce, the Kugel Hernia Patch was defective in design, making the use of the Kugel Hernia Patch more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other hernia repair patches;

c. The Kugel Hernia Patch's design defects existed before it left the control of the Defendants;

d. The Kugel Hernia Patch was insufficiently tested;

e. The Kugel Hernia Patch caused harmful side effects that outweighed any potential utility; and

f. The Kugel Hernia Patch was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.

88. In addition, at the time the Kugel Hernia Patch left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the Kugel Hernia Patch. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Kugel Hernia Patch's utility.

89. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past has suffered and will

continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
PRODUCT LIABILITY – MANUFACTURING DEFECT

90. Plaintiff incorporates by reference paragraphs 1 through 89 above, as though fully set forth herein.

91. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Kugel Hernia Patch.

92. At all times material to this action, the Kugel Hernia Patch was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including Plaintiff herein without substantial change in the condition in which it was sold.

93. At all times material to this action, the Kugel Hernia Patch was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Kugel Hernia Patch contained manufacturing defects which rendered the product unreasonably dangerous and subjected Plaintiff to risks that exceeded the benefits of the Kugel Hernia

Patch, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences;

b. The Kugel Hernia Patch's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The Kugel Hernia Patch was not made in accordance with the Defendants' specifications or performance standards; and

d. The Kugel Hernia Patch's manufacturing defects existed before it left the control of the Defendants.

94. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
PRODUCT LIABILITY - FAILURE TO WARN

95. Plaintiff incorporates by reference paragraphs 1 through 94 above, as though fully set forth herein.

96. The Kugel Hernia Patch was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with the Kugel Hernia Patch including but not limited to its propensity to cause, subjecting Plaintiff to risks that exceeded the benefits of the Kugel Hernia Patch, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other forms of hernia repair patches.

97. At the time of the Plaintiff's receipt and/or use of the Kugel Hernia Patch, the Kugel Hernia Patch was being used for the purposes and in a manner normally intended, namely for the repair of ventral and incisional hernias.

98. The Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

99. The Defendants, as manufacturers and/or distributors of the Kugel Hernia Patch, are held to the level of knowledge of an expert in the field.

100. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

101. The warnings that were given by the Defendants failed to properly warn physicians of the increased, subjecting Plaintiff to risks that exceeded the benefits of the Kugel Hernia Patch, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences.

102. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

103. The Defendants had a continuing duty to warn Plaintiff of the dangers associated with the Kugel Hernia Patch.

104. Had Plaintiff received adequate warnings regarding the risks of the Kugel Hernia Patch, she would not have used it.

105. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
PRODUCT LIABILITY – BREACH OF IMPLIED WARRANTY

106. Plaintiff incorporates by reference paragraphs 1 through 105 above, as though fully set forth herein.

107. The Defendants are liable to Plaintiff for their breach of implied warranty.

108. The Defendants designed, manufactured, marketed, distributed, supplied and sold the Kugel Hernia Patch for the repair of ventral and incisional hernias.

109. The Defendants sold the Kugel Hernia Patch which was implanted in Plaintiff.

110. At the time that the Defendants manufactured, marketed, distributed, supplied, and/or sold the Kugel Hernia Patch they knew of the use for which it was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

111. Plaintiff and plaintiff's physicians and health care providers reasonably relied on the Defendants' judgment, indications and statements that the Kugel Hernia Patch was fit for such use.

112. When the Kugel Hernia Patches were distributed into the stream of commerce and sold by the Defendants, they were unsafe for their intended use, and not of merchantable quality, as warranted by the Defendants in that they had very dangerous propensities when used as intended and implanted into a patient's body where they could cause serious injury of harm or death to the end user.

113. The Defendants knew or should have known that the Kugel Hernia Patch at the time of sale was intended to be used for the purpose of surgically implanting them into the body

for hernia repair.

114. At the time of the Plaintiff's receipt and/or use of the Kugel Hernia Patch, the Kugel Hernia Patch was being used for the purposes and in a manner normally intended, namely for the repair of ventral and incisional hernias.

115. Due to the Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the Kugel Hernia Patch until after she used it.

116. Contrary to its implied warranty, the Kugel Hernia Patch was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

117. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
BREACH OF EXPRESS WARRANTY

118. Plaintiff incorporates by reference paragraphs 1 through 117 above, as though fully set forth herein.

119. Defendants expressly warranted that the Kugel Hernia Patch was safe and/or well accepted by users.

120. The Kugel Hernia Patch does not conform to these express representations because the Kugel Hernia Patch is not safe and have numerous serious risks and side effects. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

121. Plaintiff did rely on the express warranties of the Defendants herein.

122. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of the Kugel Hernia Patch.

123. The Defendants herein breached the aforesaid express warranties, as their Kugel Hernia Patches were defective.

124. Defendants expressly represented to the users, their physicians, healthcare providers, and the FDA that the Kugel Hernia Patch was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

125. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Kugel Hernia Patch was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

126. As a result of the foregoing acts and/or omissions, the Plaintiff was and still is caused to suffer and/or at a great risk of suffering serious and dangerous side effects including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch,

and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences.

127. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

128. Plaintiff incorporates by reference paragraphs 1 through 127 above, as though fully set forth herein.

129. The Defendants are liable to Plaintiff for the negligent infliction of emotional distress.

130. Plaintiff suffered severe emotional distress, which was as a result of Defendant's negligent conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or selling of the Kugel Hernia Patch for hernia repair surgery.

131. Plaintiff suffered severe emotional distress, which was as a result of Defendant's

negligent conduct in failing to adequately and safely design and construct an effective and safe Kugel Hernia Patch for hernia repair surgery.

132. Therefore, the Defendants are liable to the Plaintiff.

133. The Defendants' conduct in continuing to market, sell and distribute the Kugel Hernia Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter the Defendants and others from similar conduct in the future.

134. As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

135. Plaintiff incorporates by reference paragraphs 1 through 134 above, as though fully set forth herein.

136. The Defendants are liable to Plaintiff for the intentional infliction of emotional

distress.

137. Plaintiff suffered severe emotional distress, which was as a result of the Defendants' extreme outrageous, intentional, willful, and reckless conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or sale of the Kugel Hernia Patch for hernia repair surgery.

138. Plaintiff suffered severe emotional distress, which was as a result of the Defendants' extreme outrageous, intentional, willful, and reckless conduct in failing to adequately and safely design and construct an effective and safe Kugel Hernia Patch for hernia repair surgery, in complete and reckless disregard of safety to Plaintiff.

139. Therefore, the Defendants are liable to Plaintiff.

140. The Defendants' conduct in continuing to market, sell and distribute the Kugel Hernia Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter the Defendants and others from similar conduct in the future.

141. As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
FRAUDULENT MISREPRESENTATION

142. Plaintiff incorporates by reference paragraphs 1 through 141 above, as though fully set forth herein.

143. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiffs, the FDA, and the public in general, that said product, the Kugel Hernia Patch, had been tested and found to be safe and effective for its intended use in repairing ventral and incisional hernias.

144. The representations made by Defendants were, in fact, false.

145. When said representations were made by Defendants, it knew the representations to be false, and it willfully, wantonly and recklessly disregarded whether the representations were true.

146. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend and use said product, the Kugel Hernia Patch, in repairing ventral and incisional hernias, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

147. At the time the aforesaid representations were made by the Defendants and, at the time that the Plaintiff used the Kugel Hernia Patch, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

148. In reliance upon said representations, the Plaintiff was induced to and did use the Kugel Hernia Patch, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

149. Said Defendants knew and were aware or should have known that the Kugel Hernia Patch had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

150. Defendants knew or should have known that the Kugel Hernia Patch had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous.

151. Defendants brought the Kugel Hernia Patch to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

152. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or are at a greatly increased risk of suffering serious and dangerous risks and side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences.

153. As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will

continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
FRAUDULENT CONCEALMENT

154. Plaintiff incorporates by reference paragraphs 1 through 153 above, as though fully set forth herein.

155. At all times during the course of dealing between Defendants and Plaintiff, Defendants misrepresented that the Kugel Hernia Patch was safe for its intended use.

156. Defendants knew or were reckless in not knowing that its representations were false.

157. In representations to Plaintiff, the FDA and healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. that the Kugel Hernia Patch was not safe for repairing ventral and incisional hernias;

b. that the risk of serious injury and side effects with the Kugel Hernia Patch were not adequately tested by Defendants;

c. that Defendants were aware of dangers with the Kugel Hernia Patch;

d. that the Kugel Hernia Patch was defective, and that it caused dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death and/or serious infections, as well as other severe and permanent health consequences;

e. that patients needed to be monitored more regularly than normal while using the Kugel Hernia Patch;

f. that the Kugel Hernia Patch was manufactured negligently;

g. that the Kugel Hernia Patch was manufactured defectively;

h. that the Kugel Hernia Patch was manufactured improperly;

i. that the Kugel Hernia Patch was designed negligently;

j. that the Kugel Hernia Patch was designed defectively; and

k. that the Kugel Hernia Patch was designed improperly.

158. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers, and the FDA the defective nature of the Kugel Hernia Patch.

159. Defendants had sole access to material facts concerning the defective nature of the Kugel Hernia Patch and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Kugel Hernia Patch, including the Plaintiff.

160. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the Kugel Hernia Patch was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and her physicians, hospitals and healthcare providers into reliance on and use of the Kugel Hernia Patch.

161. Defendants knew that Plaintiff, and her physicians, hospitals, healthcare providers, and the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the Kugel Hernia Patch, as set forth herein.

162. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposely did not include facts that were concealed and/or omitted by Defendants.

163. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer severe and/or are at a greatly increased risk of suffering serious and dangerous risks and

side effects including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, serious infection, the need for additional surgery to remove and replace the Kugel Hernia Patch, and/or the need for additional surgery to repair a perforation caused by the "memory recoil ring", as well as other severe and permanent health consequences.

164. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XI
NEGLIGENT MISREPRESENTATION

165. Plaintiff incorporates by reference paragraphs 1 through 164 above, as though fully set forth herein.

166. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, the Kugel Hernia Patch, had been tested and found to be safe and effective for repairing ventral and incisional hernias.

167. The representations made by Defendants were, in fact, false.

168. Defendants failed to exercise ordinary care in the representation of the Kugel Hernia Patch, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented the Kugel Hernia Patch's high risk of unreasonable, dangerous side effects.

169. Defendants breached their duty in representing the Kugel Hernia Patch's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

170. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that the Kugel Hernia Patch had been insufficiently tested, that it had not been tested, that it lacked adequate warnings, and/or that it created a high risk of unreasonable, dangerous side effects, including but not limited to bowel perforations, bowel obstructions, chronic intestinal fistulae, death, and severe infections, as well as other severe and permanent health consequences.

171. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XII
FRAUD AND DECEIT

172. Plaintiff incorporates by reference paragraphs 1 through 171 above, as though fully set forth herein.

173. Defendants conducted research and used the Kugel Hernia Patch as part of their research.

174. As a result of Defendants' research and testing, or lack thereof, Defendants distributed blatantly and intentionally false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and the FDA that the Kugel Hernia Patch was safe to use as a means of repairing ventral and incisional hernias.

175. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

176. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their respective healthcare providers and/or the FDA.

177. The information distributed to the public, the FDA and the Plaintiff, by Defendants, including but not limited to reports and press releases, contained material representations of fact and/or admissions.

178. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' Kugel Hernia Patch was safe for use in repairing ventral and incisional hernias.

179. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that the Kugel Hernia Patch was not injurious to the health and/or safety of its intended users.

180. These representations were false and misleading.

181. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that the Kugel Hernia Patch was not safe as a means of repairing ventral and incisional hernias.

182. Defendants intentionally made material representations to the FDA and the public, including the medical profession, the Plaintiff regarding the safety of the Kugel Hernia Patch, specifically but not limited to the Kugel Hernia Patch not having dangerous and serious health and/or safety concerns.

183. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and the Plaintiff, to gain the confidence of the public, the FDA, and the Plaintiff, to falsely ensure the quality and fitness for use of the Kugel Hernia Patch and induce the public, and the Plaintiff to use the Kugel Hernia Patch.

184. That Defendants made claims and representations in its documents submitted to the FDA, to the public, and the Plaintiff, that the Kugel Hernia Patch did not present serious health and/or safety risks.

185. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

186. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, and were made in order to induce the Plaintiff to rely upon misrepresentations and caused the Plaintiff to use and rely on the Kugel Hernia Patch.

187. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of the Kugel Hernia Patch to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective.

188. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of the Kugel Hernia Patch by concealing the suppressing material facts regarding the dangerous and serious health and/or safety concerns of the Kugel Hernia Patch.

189. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff into a sense of security so that Plaintiff would rely on the representations and purchase, use, and rely on the Kugel Hernia Patch and/or that their respective healthcare providers would do the same.

190. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, would rely upon the information being disseminated.

191. That the Plaintiff did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of hernia repair patches, and were thereby induced to purchase, use and rely on Defendants' Kugel Hernia Patch.

192. That at the time the representations were made, the Plaintiff did not know the truth with regard to the dangerous and serious health and/or safety concerns of the Kugel Hernia Patch.

193. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

194. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of the Kugel Hernia Patch, Plaintiff would not have used and/or relied on Defendants' Kugel Hernia Patch.

195. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly, and/or purposefully on the Plaintiff.

196. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XIII
VIOLATIONS OF NEW YORK GBL §§ 349 and 350

197. Plaintiff incorporates by reference paragraphs 1 through 195 above, as though fully set forth herein.

198. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

199. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

200. The Defendants are designers, manufacturers, promoters, marketers, developers, sellers and/or distributors of the Kugel Hernia Patch.

201. The Defendants knew, or should have known, that the Kugel Hernia Patch was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life-threatening side effects.

202. Notwithstanding the foregoing, the Defendants omitted material facts in the disclosures it made to the public, the medical community and to consumers, including Plaintiff herein, concerning the use and safety of the Kugel Hernia Patch.

203. Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff and/or Plaintiff's physicians.

204. The Defendants' practice of promoting the Kugel Hernia Patch created and/or reinforced a false impression as to its safety.

205. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

206. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective and dangerous, and by other acts alleged herein.

207. The Defendants' practice of promoting the Kugel Hernia Patch placed and continues to place all consumers of the Kugel Hernia Patch at risk for serious injury and potentially lethal side effects.

208. Plaintiff used the Kugel Hernia Patch for personal purposes and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

209. Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff and/or Plaintiff's physicians.

210. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350, Plaintiff has suffered damages, for which she is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

211. As a direct and proximate result of the Defendants' acts of consumer fraud, Plaintiff has suffered ascertainable loss – economic loss that includes the purchases of the Kugel Hernia Patch and additional out-of-pocket healthcare related costs – for which the Defendants are liable to Plaintiff for treble their actual damages.

212. As a direct and proximate of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XIV
PUNITIVE DAMAGES UNDER COMMON LAW

213. Plaintiff incorporates by reference paragraphs 1 through 212 above, as though fully set forth herein.

214. At all times material hereto, the Defendants knew or should have known that the Kugel Hernia Patch was inherently more dangerous with respect to the risks of bowel perforations, bowel obstructions, chronic intestinal fistulae, death and/or other side effects such as serious infection than other similar products.

215. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Kugel Hernia Patch.

216. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff herein, concerning the safety of the Kugel Hernia Patch.

217. At all times material hereto, the Defendants knew and recklessly disregarded the fact that the Kugel Hernia Patch causes bowel perforations, bowel obstructions, chronic intestinal fistulae, death and/or other side effects such as serious infection with greater frequency than other products used in hernia repair.

218. Notwithstanding the foregoing, the Defendants continued to aggressively market the Kugel Hernia Patch to consumers, including Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternative available for use in hernia repair.

219. The Defendants knew of the Kugel Hernia Patch's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by the Kugel Hernia Patch.

220. Defendants intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiff herein, the potentially life threatening side effects of the Kugel Hernia Patch in order to ensure continued and increased sales.

221. The Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the Kugel Hernia Patch against its benefits.

222. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, and the unreasonably dangerous and defective characteristics of the Kugel Hernia Patch, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

223. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against each of the Defendants as follows:

a. Awarding actual damages to the Plaintiff incidental to Plaintiff's use of the Kugel Hernia Patch in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to the Plaintiff;

c. Awarding pre-judgment and post-judgment interest to the Plaintiff;

d. Awarding the costs and the expenses of this litigation to the Plaintiff;

e. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

f. Granting all such other relief as the Court deems necessary, just and proper.

Date: Great Neck, New York
March 25, 2008

Respectfully submitted,

PARKER WAICHMAN ALONSO, LLP

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Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

_____
MELANIE H. MUHLSTOCK (MM-9309)